UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE: NEW ENGLAND COMPOUNDING PHARMACY, INC. PRODUCTS LIABILITY LITIGATION THIS DOCUMENT RELATES TO: All Actions	MDL No. 2419 Master Docket No.: 1:13-md-2419-FDS Honorable F. Dennis Saylor DEMAND FOR JURY TRIAL

FIRST AMENDMENT TO MASTER COMPLAINT

Pursuant to Rule 15(a)(B) of the Federal Rules of Civil Procedure, the Plaintiffs' Steering Committee hereby files this First Amendment to the Master Complaint. This amendment is intended to add to the Master Complaint a Civil Conspiracy Count (Count XI-A) specifically against Saint Thomas Outpatient Neurosurgical Center, Howell Allen Clinic, Debra Schamberg, R.N. and John Culclasure, M.D. All other allegations of the Master Complaint remain unchanged.

COUNT XI-A – CIVIL CONSPIRACY
(Against Clinic Related Defendants)

364. All allegations in the original Master Complaint are incorporated herein by reference.

365. Defendant Saint Thomas Outpatient Neurosurgical Center, LLC, ("Saint Thomas Clinic") is a Tennessee for-profit limited liability company organized and domesticated under the laws of the State of Tennessee. Saint Thomas Clinic's principal place of business is located on the 9th floor of the Medical Plaza East office building on the Saint Thomas Hospital campus at 4230 Harding Pike in Nashville, Davidson County, Tennessee 37205. Saint Thomas

Clinic's registered agent for service of process is Gregory B. Lanford, M.D., 2011 Murphy Avenue, Suite 301, Nashville, Tennessee 37203.

366. Defendant Howell Allen Clinic A Professional Corporation, ("Howell Allen Clinic") is a Tennessee professional corporation organized and domesticated under the laws of the State of Tennessee with its principal place of business located in Nashville, Davidson County, Tennessee. Howell Allen Clinic's registered agent for service of process is Gregory B. Lanford, M.D., 2011 Murphy Avenue, Suite 301, Nashville, Tennessee 37203. Howell Allen Clinic owns one-half of Saint Thomas Clinic and receives one-half of that company's profits.

367. Defendant John Culclasure, M.D., ("Dr. Culclasure") is an individual residing at 1510 Demonbreun Street, Unit 1208, Nashville, Tennessee 37203 and a citizen and resident of the State of Tennessee. During all relevant times, Dr. Culclasure was an employee of the Howell Allen Clinic and the Medical Director of Saint Thomas Clinic. Dr. Culclasure is a medical doctor and practices in the specialty of anesthesiology. Dr. Culclasure was involved in the day to day operations at Saint Thomas Clinic.

368. Defendant Debra Schamberg, R.N., ("Ms. Schamberg") is an individual residing at 2644 Mossdale Drive, Nashville, Tennessee 37217 and a citizen and resident of the State of Tennessee. During all relevant times, Debra Schamberg was an employee of Howell Allen Clinic and the Facilities Director of Saint Thomas Clinic. Ms. Schamberg is a registered nurse and was involved in the day to day operations at Saint Thomas Clinic.

369. The decision by Saint Thomas Clinic to have NECC produce MPA for the clinic was made by Dr. Culclasure (the clinic's Medical Director) and Ms. Schamberg (the clinic's Facilities Director). Dr. Culclasure and Ms. Schamberg were employees of Howell Allen Clinic at the time that they made that decision, and they were acting within the course and

scope of their employment. Howell Allen Clinic is responsible for decisions made by Dr. Culclasure and Ms. Schamberg pursuant to the doctrine of *respondeat superior* and principles of agency. Dr. Culclasure and Ms. Schamberg were also duly authorized agents of Saint Thomas Clinic and where acting on the clinic's behalf as its Medical Director and Facilities Director. Saint Thomas Clinic is responsible for Dr. Culclasure's and Ms. Schamberg's decisions under principles of agency.

370. Saint Thomas Clinic, Howell Allen Clinic, Dr. Culclasure and Ms. Schamberg are hereinafter collectively referred to as "the Saint Thomas Clinic Defendants."

371. The Saint Thomas Clinic Defendants knew that NECC was a compounding pharmacy. The FDA defines pharmacy compounding as follows:

> FDA regards traditional pharmacy compounding as the extemporaneous combining, mixing or altering of ingredients by a pharmacist in response to a physician's prescription to create a medication tailored to the specialized medical needs of an individual patient.

2006 Limited FDA Survey of Compounded Drug Products (emphasis added).

372. MPA is a prescription drug defined by 105 CMR § 700.002(F) as a *Schedule VI* controlled substance.

373. The FDA considers MPA to be a "prescription drug."[1]

374. The Saint Thomas Clinic Defendants knew that MPA is a prescription drug.

375. The external packaging for MPA provided by NECC to Saint Thomas Clinic, as well as the external packaging for Depo-Medrol®, a brand name form of MPA manufactured by Pfizer, both indicate that MPA is a prescription drug.

376. The Saint Thomas Clinic Defendants acted in concert with NECC, and with NECC's agents and employees, to accomplish the common and unlawful purpose of violating

[1]http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.Overview&DrugName=METHYLPREDNISOLONE%20ACETATE

Massachusetts Board of Registration in Pharmacy ("Massachusetts Board of Pharmacy") requirements prohibiting the distribution of MPA, a Schedule VI controlled substance, without patient specific prescriptions. Some of those requirements are referenced in an *ADVISORY* issued by the Massachusetts Board of Pharmacy. That *ADVISORY* is attached hereto as Exhibit 1 and incorporated herein by reference.

377. The Saint Thomas Clinic Defendants and NECC accomplished their common design via the unlawful means of using certain patient lists to accompany orders of MPA. The Saint Thomas Clinic Defendants used those patient lists even though some of the names listed were for patients who did not receive MPA and some of the names were fictitious, such as "Mickey Mouse." The Saint Thomas Clinic Defendants undertook those overt acts in furtherance of the conspiracy.

378. The Saint Thomas Clinic Defendants knew that patient specific prescriptions were required in order for NECC to produce MPA lawfully. For example, NECC's standard order form for MPA and other drugs requested patient specific information. Instead of filling out those standard forms properly, the Saint Thomas Clinic Defendants ordered NECC pharmaceuticals in bulk and thereafter submitted lists of patient names, regardless of whether the listed patients actually received the drug. Sometimes those lists included fictitious names such as "Mickey Mouse."

379. The Saint Thomas Clinic Defendants were aware of NECC's intent to use the subject patient lists in order to subvert Massachusetts Board of Pharmacy requirements. For example, in early to mid-2012, an NECC representative informed Ms. Schamberg that NECC needed to receive lists of patients with each order for MPA. The NECC representative explained that NECC needed those lists in order to comply with Massachusetts Board of Pharmacy

requirements. Ms. Schamberg then told the NECC representative that she could not predict which patients would receive MPA and therefore could not provide lists that would actually correspond with patients who receive MPA. In response, the NECC representative indicated that any list of patient names would suffice.

380. In response to NECC's request for assistance in papering over Massachusetts Board of Pharmacy requirements, Saint Thomas Clinic Defendants sent NECC lists of patients' names and addresses even though the listed patients did not necessarily receive MPA. Some of those lists contained fictitious names, including Mickey Mouse.

381. Saint Thomas Clinic Defendants' conduct in forwarding lists of patient names and addresses to NECC, even though those names did not correspond with patients who received MPA, violated Title II of the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), Public Law 104-191, as amended, and the regulations related thereto codified in the Code of Federal Regulations Title 45, Subtitle A, Subchapter C, including 45 C.F.R. § 164.502. Saint Thomas Clinic Defendants engaged in that unlawful conduct in order to enhance clinic profits. Saint Thomas Clinic Defendants wanted to purchase MPA from the cheapest source possible regardless of whether the producer's methods were underhanded and illegal.

382. A true and correct copy of a verified interrogatory response by Saint Thomas Clinic discussing its communications with NECC and its use of patient lists is attached as Exhibit 2. That interrogatory response, dated April 30, 2013, was the first time that any Plaintiff had reason to know of the Saint Thomas Clinic Defendants' participation in the subject conspiracy.

383. Attached hereto as Exhibit 3 are hand written notes by Ms. Schamberg, Facilities Director of Saint Thomas Clinic, recording her affirmative knowledge that NECC requested patient lists in order to comply with Massachusetts Board of Pharmacy requirements.

384. The Saint Thomas Clinic Defendants knew or should have known that Tennessee law likewise requires individual prescriptions when procuring prescription drugs produced by a compounding pharmacy.

385. The Saint Thomas Clinic Defendants and NECC knew of each other's common intent to use the subject patient lists in order to circumvent the Massachusetts, Tennessee and federal prescription requirements.

386. The conspiracy among NECC and the Saint Thomas Clinic Defendants was a proximate and legal cause of harm to Plaintiffs. If the Saint Thomas Clinic Defendants and NECC had abided by the law requiring individual prescriptions, then NECC could not and would not have produced and sold MPA in bulk. Mass producing MPA and selling it across the country in bulk, while abiding by the individual prescription rule, was not logistically possible. The Saint Thomas Clinic Defendants conspired with NECC, in violation of the individual prescription rule, because the Saint Thomas Clinic Defendants desired to buy MPA from the cheapest and easiest source, thereby enhancing clinic profits. Rather than participating in the subterfuge of papering over the individual prescription rule by unlawfully sending the subject patient lists to NECC, the Saint Thomas Clinic Defendants should have declined to conspire with NECC. The Saint Thomas Clinic Defendants could have purchased MPA from a reputable, FDA regulated drug manufacturer such as Pfizer. Purchasing Depo-Medrol® was safer, although slightly more expensive. If the Saint Thomas Clinic Defendants had chosen to purchase Depo-

Medrol®, the safer name brand version of MPA manufactured by Pfizer, the entire fungal meningitis outbreak would have been avoided.

387. The Saint Thomas Clinic Defendants are liable for the acts of their co-conspirator NECC.

WHEREFORE, the Plaintiffs demand judgment against Saint Thomas Clinic Defendants, jointly and severally, on Count XI-A of this Complaint, in an amount that will justly compensate them for their damages, together with interest, costs and attorneys' fees incurred in this action, all within the jurisdictional limits of this Court.

Respectfully submitted,

LEADER, BULSO & NOLAN, PLC

Dated: January 31, 2014

/s/ **George Nolan**
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As Vice Chair for Tennessee and designated counsel on behalf of the Plaintiffs' Steering Committee

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Plaintiffs' Steering Committee

CERTIFICATE OF SERVICE

I, George Nolan, hereby certify that I caused a copy of the foregoing to be filed electronically via the Court's electronic filing system. Those attorneys who are registered with the Court's electronic filing system may access these filings through the Court's system, and notice of these filings will be sent to these parties by operation of the Court's electronic filing system.

/s/ **George Nolan**
George Nolan